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Application Number	10/611,459
Filing Date	July 1, 2003
First Named Inventor	Keith Robert Hildebrand
Group Art Unit	1616
Examiner Name	T/B/D
Attorney Docket Number	11738.00161

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**Examiner
Signature**

S Kennedy

Date Considered

2/7/05

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SK		Menkes, D B, et al.; "Sodium Valproate for Tinnitus"; Journal of Neurology Neurosurgery & Psychiatry, XX, XX, vol. 65, no. 5, November 1998 (1998-11) page 803.	
		Simpson, J J, et al.; "A Review of Evidence in Support of a Role for 5-HT in the Perception of Tinnitus"; Hearing Research 2000 Netherlands, vol. 145, no. 1-2, 2000, pages 1-7.	
		Uno, I, et al.; "A Rare Complication of Stellate Ganglion Block a Case Report"; Practica Otologica Kyoto; vol. 77, no. 12, 1984, pages 2515-2519.	
		Gentili, Marc E.; "Epidural Fibrin Glue Injection Stops Postdural Puncture Headache in Patient With Long-Term Intrathecal Catheterization."; Regional Anesthesia and Pain Medicine, United States 2003; Jan-Feb, vol. 28, no. 1; January 2003 (2003-01), page 70.	
SK		Coffey, R J, et al.; "Abrupt Intrathecal Baclofen Withdrawal: Management of Potentially Life-Threatening Sequelae"; Neuromodulation 2001 United States, vol. 4, no. 4, 2001, pages 142-146.	

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Sheet	/	of	/	Attorney Docket Number	11738.00161

U.S. PATENT DOCUMENTS					
Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
SK		US-5,496,369	03-05-1996	Howard, III	
SK		US- 5,676,655	10-14-1997	Howard, III et al.	
SK		US- 5,713,847	02-03-1998	Howard, III et al.	
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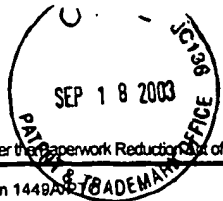
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Examiner Signature	<i>SKennedy</i>	Date Considered	2/5/05
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JK		LEWIS, J.E., S.D.G. STEPHENS, ET AL., "Tinnitus and suicide." July 7, 1993, pgs. 50-54, vol. 19, Clin Otolaryngol.	
		MCFADDEN, D., Tinnitus: Facts, Theories, and Treatments, 1982, pgs. 1-9, National Academy Press, Washington D.C.	
		SATALOFF, J., R.T. SATALOFF, ET AL., "Tinnitus and vertigo in healthy senior citizens without a history of noise exposure." March 1987, pgs. 87-89, vol. 2, Thieme Medical Publishers, Inc., New York, NY	
		AXELSSON, A. and A. RINGDAHL, "Tinnitus-a study of its prevalence and characteristics." 1989, pgs. 53-56, vol. 23, British Journal of Audiology	
		COLES, R. R. A., THOMPSON, ET AL., "Intra-tympanic injections in the treatment of tinnitus." 1992, pgs. 240-242, vol. 17, Clin Otolaryngol.	
		DOBIE, R.A., "A review of randomized clinical trials in tinnitus." The Laryngoscope, August 1999, pgs. 1202-1211, Lippincott Williams & Wilkins, Inc., Philadelphia.	
		LOCKWOOD, A.H., R.J. SALVI, ET AL., "The functional neuroanatomy of tinnitus: Evidence for limbic system links and neural plasticity." January, 1998, Neurology, pgs. 114-120, vol. 50, American Academy of Neurology.	
		MOLLER, A.R., "Symptoms and signs caused by neural plasticity." Neurological Research, September, 2001, pgs. 565-572, vol. 23, Forefront Publishing Group.	
		DEN HARTIGH, J., C. G. J. M. HILDERS, ET AL., "Tinnitus suppression by intravenous lidocaine in relation to its plasma concentration." Clinical Pharmacology & Therapeutics, October 1993, pgs 415-420, vol. 54 no. 4, Mosby-Year Book, Inc.	
		OCHI, K. and J.J. EGGERMONT, "Effects of salicylate on neural activity in cat primary auditory cortex." Hearing Research, 1996, pgs 63-76, vol. 95, Elsevier Science B.V.	
		CASPARY, D.M., J. C. MILBRANDT, ET AL., "Central Auditory Aging: GABA Changes in the Inferior Colliculus." Experimental Gerontology, 1995, pgs. 349-360, vol. 30 nos. 3/4, Elsevier Science Ltd., USA.	
		MCGEER, E. G. and P. L. MCGEER, "AGE CHANGES IN THE HUMAN FOR SOME ENZYMES ASSOCIATED WITH METABOLISM OF THE CATECHOLAMINES, GABA AND ACETYLCHOLINE." Neurobiology of Aging, 1975, pgs. 287-305, Plenum Press, New York.	
		RAZA, A., J. C. MILBRANDT, ET AL., "Age-Related Changes in Brainstem Auditory Neurotransmitters: Measures of GABA and Acetylcholine Function." Hearing Research, 1994, pgs. 221-230, vol. 77, Elsevier Science B. V.	
		ARAKI, T., H. KATO, ET AL., "Selective changes of neurotransmitter receptors in middle-aged gerbil brain." Neurochem. Int., 1993, pgs. 541-548, vol. 23 no. 6, Pergamon Press Ltd.	
		MILDBRANDT, J. C., R. L. ALBIN, ET AL., "Age-Related Decrease in GABA _A Receptor Binding in the Fischer 344 Rat Inferior Colliculus." Neurobiology of Aging, 1994, pgs. 699-703, vol. 15 no. 6, Elsevier Science Ltd., USA.	
		MOLLER, A. R., M. B. MOLLER, ET AL., "Some Forms of Tinnitus May Involve the Extralemniscal Auditory Pathway." Laryngoscope, October 1992, pgs. 1165-1171.	
		SZCZEPANIAK, W. S. and A. R. MOLLER, "EFFECTS OF L-BACLOFEN AND D-BACHLOFEN ON THE AUDITORY SYSTEM: A STUDY OF CLICK-EVOKED POTENTIALS FROM THE INFERIOR COLLICULUS IN THE RAT." Ann Otol Rhinol Laryngol, 1995, pgs. 399-404.	
		SZCZEPANIAK, W. S. and A.R. MOLLER, "Effects of (-) baclofen, clonazepam, and diazepam on tone exposure-induced hyperexcitability of the inferior colliculus in the rat: possible therapeutic implications for pharmacological management of tinnitus and hyperacusis." Hearing Research, 1996, pgs. 46-53, Elsevier Science B.V.	
JK		LEES, A. J., C. R. CLARKE, ET AL., "HALLUCINATIONS AFTER WITHDRAWAL OF BACLOFEN." The Lancet, April 16, 1977.	



SK	ZAPP, J. J., "Gabapentin for the treatment of tinnitus: A case report." ENT-Ear, Nose & Throat Journal, February 2001, pgs. 114-118.
	KUZNIECKY, R., S. HO, ET AL., "Modulation of cerebral GABA by topiramate, lamotrigine, and gabapentin in healthy adults." Neurology, February 2002, pgs. 368-372, AAN Enterprises, Inc.
	PETROFF, O. A., F. HYDER, ET AL., "Effects of Gabapentin on Brain GABA, Homocarnosine, and Pyrrolidone in Epilepsy Patients." Epilepsia, 2000, pgs. 675-680, Lippincott Williams & Wilkins, Inc., Baltimore.
	WESTERBERG, B. D., J. B. ROBERSON, ET AL., "A double-blind placebo-controlled trial of baclofen in the treatment of tinnitus." The American Journal of Otology, 1996, pgs. 896-903, The American Journal of Otology, Inc.
	COFFEY, R. J., D. CAHILL, ET AL., "Intrathecal baclofen for intractable spasticity of spinal origin: results of a long-term multicenter study." J Neurosurg, February 1993, pgs. 226-232, vol. 78.
	MEYTHALER, J. M., S. GUIN-RENFROE, ET AL., "CONTINUOUSLY INFUSED INTRATHECAL BACLOFEN FOR SPASTIC/DYSTONIC HEMIPLEGIA." American Journal of Physical Medicine & Rehabilitation, 1999, pgs. 155-161, no. 8, Lippincott Williams & Wilkins, Inc.
	PENN, R. D., S. M. SAVOY, ET AL., "INTRATHECAL BACLOFEN FOR SEVERE SPINAL SPASTICITY." New England Journal of Medicine, June 8, 1989, pgs. 1571-1521, vol. 320.
	KNUTSSON, E., U. LINDBLOM, ET AL., "Plasma and Cerebrospinal Fluid Levels of Baclofen (Lioresal®) at Optimal Therapeutic Responses in Spastic Paresis." Journal of the neurological Sciences, 1974, pgs. 473-484, vol. 23, Elsevier Scientific Publishing Company, Netherlands.
	KROIN, J. S., "Intrathecal Drug Administration." Clin. Pharmacokinet. 1992, pgs. 319-326, vol. 22 (5), Adis International Limited.
	KROIN, J. S. and R.D. PENN, "Cerebrospinal fluid pharmacokinetics of lumbar intrathecal baclofen", 1991, pgs. 67-77, Parthenon Publishing.
	MULLER, H., J. ZIERSKI, ET AL. "Pharmacokinetics of Intrathecal Baclofen." 1998, pgs. 223-226, Springer-Verlag.
	MILBRANDT, JC, ET AL., "GAD levels and muscimol binding in rat inferior colliculus following acoustic trauma." Hearing Research, 2000, pgs. 251-260, vol. 147 (1-2), Elsevier Science B.V.
	CASPARY, D.M., T.M. HOLDER, ET AL. "AGE-RELATED CHANGES IN GABA _A RECEPTOR SUBUNIT COMPOSITION AND FUNCTION IN RAT AUDITORY SYSTEM." Neuroscience, 1999, pgs. 307-312, vol. 93, Elsevier Science, Ltd.
	MILBRANDT JC, HUNTER C, ET AL., "Alterations of GABA _A Receptor Subunit mRNA Levels in the Aging Fischer 344 Rat Inferior Colliculus." The Journal of Comparative Neurology, 1997, pgs 455-65, vol. 379, Wiley-Liss, Inc.
	MILBRANDT JC, ET AL., "GABA _A RECEPTOR BINDING IN THE AGING RAT INFERIOR COLLICULUS." Neuroscience, 1998, pgs. 449-458, vol. 73, no. 2, Elsevier Science Ltd., Great Britain.
	SIMPSON, J.J. ET AL. "Recent advances in the pharmacological treatment of tinnitus." Trends in Pharmacology Sciences, January 1999, vol. 20.
	JASTREBOFF, P., ET AL., "Neurophysiological approach to tinnitus patients." The American Journal of Otology, 1998, pgs. 236-240, vol. 17, The American Journal of Otology, Inc.
	MERCHANT, S.N. ET AL., "Vestibular effects of intravenous lidocaine used in the treatment of tinnitus." The Journal of Laryngology and Otology, November 1986, pgs. 1249-1253, vol. 100.
	PODOSHIN, L. M. ET AL., "Treatment of tinnitus by intratympanic installation of lignocaine (lidocaine) 2 per cent through ventilation tubes." The Journal of Laryngology and Otology, July 1992, pgs. 603-606, vol. 106.
	RAZA, A., ET AL., "Age-related changes in brainstem auditory neurotransmitters: measures of GABA and acetylcholine function." Hearing Research, 1994, pgs. 221-230, vol. 77, Elsevier Science B.V.
SK	KALTENBACH, J. A. "Neurophysiologic Mechanisms of Tinnitus." Journal of the American Academy of Audiology, March 2000, pgs. 125-137, vol. 11, no. 3.

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